REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 1, 8 and 13 have been amended. The amendment to claims 1, 8 and 13 is supported by the original disclosure, for example, by original claims 5, 12 and 17 and at page 5, lines 4-14 of the specification. Claims 5, 12 and 17 have been canceled without prejudice or disclaimer. No new matter has been added. Claims 1, 7-8, 13 and 18-19 are pending.

Claim rejections - 35 U.S.C. § 103

Claims 1, 5, 8, 12, 13 and 17 are rejected as unpatentable over U.S. Patent Application Publication No. 2005/0106748 (Proffitt et al.). Applicant respectfully traverses the rejection.

Claim 1 recites that the albumin in urine is assayed in a solution having a pH equal to or below the pKa of the protein indicator, that the protein assay indicator in the solution is from colorless to light orange in color when no albumin is present in the solution, and that the protein assay indicator in the solution is from red to purple in color when albumin is present in the solution.

Albumin is often times present in urine in very low concentrations. According to the method of claim 1, albumin in very low concentrations can be detected accurately in urine. That is, in the method of assaying albumin in urine according to the features of claim 1, the protein assay indicator before assaying for urine is from colorless to a light color. Once urine that contains albumin is assayed, the protein assay indicator changes from colorless/light color to red/purple. Thus, a distinct change in color can be achieved even where there is a very low concentration of albumin. This distinct change in color allows better accuracy than the color change from, for example, yellow to blue, as is the case in assays that use TBPB, which often times leads to erroneous evaluations due to the similarity in the color where low concentrations of albumin is present. Therefore, when albumin in urine is assayed in accordance with claim 1, albumin even at very low concentrations can be detected accurately, regardless of whether the evaluation is visual or a measurement apparatus is used.

Proffitt is focused on a method of enhancing the transolubility of organic acid reagents, and is silent as to the use of Chemical Formulas (1)-1 and (1)-2 for assaying albumin in urine as recited in claim 1. While Proffitt provides an example where pyrogallol red dye is used for detecting protein, the reference in no way teaches or suggests that pyrogallol red dye is

interchangeable with any of the other organic acid reagents listed by Proffitt as candidates for reagents that can be used in the method of enhancing the transolubility of organic acid reagents as taught by Proffitt.

Moreover, nothing in Proffitt teaches or suggests limiting the pH of a solution in which the albumin in urine is assayed to equal to or lower than the pKa of the protein indicator as recited in claim 1so that a distinct color change from colorless/light color to red/purple can be achieved when the albumin in urine is assayed. As indicated above, such a color change allows very low concentrations of albumin in urine to be detected accurately. Nothing in Proffitt teaches or suggests the advantages of claim 1.

In fact, Applicant submits that one would not expect that albumin in urine could be detected accurately from the teachings of Proffitt, and in fact, one would expect just the opposite: that is, one would expect that there would be inaccurate evaluations using the method of Proffitt for the detection of albumin in urine. That is, as indicated above, albumin in urine is often times present in very low concentrations. One would not expect that very low concentrations of albumin could be detected using the method of Proffitt.

Specifically, Proffitt teaches that in general, their method involves mixing an organic acid reagent and an amine to form a salt complex, dissolving the salt complex in an aqueous/organic solvent to release the organic reagent into the solvent, and then applying the solvent to the diagnostic test device. Applicant submits that if phloxine B is used in the method as taught by Proffitt, one would expect the phloxine B to be thoroughly dissolved but scantly dispersed in each of the aqueous, organic and mixture of aqueous and organic solvents. As such, one in fact would not expect that a color change from colorless/light color to red/purple could be achieved where very low concentrations of albumin such as in urine are being assayed. Nothing in Proffitt teaches or suggests the features of claim 1 or the benefits. Accordingly, claim 1 and its dependent claims are patentable over Proffitt.

Claim 8 is directed to a protein assay indicator for assaying albumin in urine. Claim 8 recites that the protein assay indicator in a solution is from colorless to light orange in color when no albumin is present in the solution, that the protein assay indicator in the solution is from red to purple in color when albumin is present in the solution, and that the solution has a pH equal to or below the pKa of the protein indicator. When the protein assay indicator as

recited in claim 8 is used for assaying albumin in urine, a strong color change is observed such that even very low concentrations of albumin can be detected accurately.

The rejection appears to contend since Proffitt teaches an indicator (phloxine B) that corresponds to Chemical Formula (1)-1, the limitations of the color at a particular pH and in the presence of protein are being read as inherent features of the claimed compound. However, when Proffitt is understood as a whole, Proffitt would not have yielded a predictable result of a protein assay indicator for assaying albumin in urine as recited in claim 8, or the advantages.

Proffitt is focused on providing a method of enhancing the transolubility of organic acid reagents in general, and is silent as to the particular functions of the large number of organic acid reagents listed in paragraph [0038] of Proffitt other than pyrogallol red dye. Proffitt fails to provide any basis to show that there would have been a reasonable expectation of success in achieving a protein assay indicator as recited in claim 8, and achieve superior sensitivity in the detection of albumin in urine. Accordingly, claim 8 and its dependent claims are patentable over Proffitt.

Claim 13 is directed to a test piece used for quantifying or semi-quantifying albumin in urine. Claim 13 recites that the test piece includes a protein assay indicator, that the protein assay indicator in a solution is from colorless to light orange in color when no albumin is present in the solution, that the protein assay indicator in the solution is from red to purple in color when albumin is present in the solution, and that the solution has a pH equal to or below the pKa of the protein indicator. When the test piece as recited in claim 8 is used for assaying albumin in urine, a strong color change is observed such that even very low concentrations of albumin can be detected accurately.

Proffitt is focused on providing a method of enhancing the transolubility of organic acid reagents in general, and is silent as to the particular functions of the large number of organic acid reagents listed in paragraph [0038] of Proffitt other than pyrogallol red dye.

Moreover, Applicant submits that one would question whether albumin in urine could be detected using the test piece as taught by Proffitt. That is, as is clear from the above discussion, Proffitt teaches that the organic reagent is thoroughly dissolved but scantly dispersed in each of the aqueous, organic and mixture of aqueous and organic solvents before applying the solvent to the diagnostic test device. As such, one in fact would question

whether albumin, which is often times present in very low concentrations in urine, could be detected in urine using the test piece of Proffitt. Therefore, when Proffitt is understood as a whole, Proffitt would not have yielded a predictable result of a test piece for assaying albumin in urine as recited in claim 13, or the advantages. Accordingly, claim 13 and its dependent claims are patentable over Proffitt.

Claim 7 is rejected under 35 USC 103(a) as being unpatentable over Proffitt et al. in view of Lau (EP 0,361,244). Applicant respectfully traverses the rejection.

Claim 1 has been distinguished above over Proffitt. Lau does not remedy the deficiencies of Proffitt. Claim 7 depends from claim 1 and is patentable over Proffitt and Lau for at least the same reasons discussed above for claim 1. Applicant does not concede the correctness of the rejection.

Claims 18 and 19 are rejected under 35 USC 103(a) as being unpatentable over Proffitt et al. in view of Albarella et al. (US 5,424,215). Applicant respectfully traverses the rejection.

Claim 13 has been distinguished above over Proffitt. Albarella does not remedy the deficiencies of Proffitt. Claims 18 and 19 depend from claim 13 and are patentable over Proffitt and Albarella for at least the same reasons discussed above for claim 13. Applicant does not concede the correctness of the rejection.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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